

Attorney Docket No.: PENN-0786
Inventors: Greene et al.
Serial No.: 09/977,716
Filing Date: October 15, 2001
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REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Claim 1 has been amended. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Provisional Obviousness-type Double Patenting Rejection

The Examiner has maintained the provisionally obviousness-type double patenting rejection of claim 1 over claims 11-14 of co-pending Application No. 09/783,896. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are filing a terminal disclaimer with respect to co-pending Application No. 09/783,896 herewith. Withdrawal of this rejection is therefore respectfully requested.

II. Information Disclosure Statement

The Examiner maintains that references AA-AD of the IDS which have been lined through in the copy of the Information Disclosure Statement provided with the last Office Action will not be considered because copies of the references were not provided with the application. As pointed out in the last response, copies of these references were already provided in prior pending U.S. patent applications and provision of

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additional copies should not be required. Further, Applicants do not believe that these references are pertinent to the novelty or unobviousness of the claimed invention. However, in an earnest effort to facilitate the prosecution of this case, Applicants are providing herewith courtesy copies of references AA, AC and AD. Reference AB is reference text not relevant to the novelty or obviousness of the claimed invention and therefore is not being provided herewith.

III. Rejection of Claim 1 under 35 U.S.C. § 112, second paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that the phrase "which binds directly to RNA" is vague and indefinite because the Examiner suggests that it is unclear whether the amplified oligonucleotide is RNA or not.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to clarify that the oligonucleotide is amplified by RNA amplification. Support for this amendment is found in the specification at page 14, lines 11-26 wherein it is taught that a preferred means for detection comprises staining with a fluorescent dye after RNA

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amplification. RNA amplification followed by contacting the RNA product with the fluorescent dye is also explicitly taught in Example 5 of the application beginning at page 26. Thus, no new matter is added by this amendment.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the amendment to claim 1.

IV. Rejection of Claim 1 under 35 U.S.C. § 102(b)

Claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Sano et al. (U.S. Patent 5,665,539). Applicants respectfully traverse this rejection.

As acknowledged by the Examiner, Sano et al. teaches an immuno-PCR assay. Further, as acknowledged by the Examiner, Sano et al. teaches use of ethidium bromide, a well known DNA binding dye for detection of their amplified DNA product.

In contrast, the fluorescent dyes used in the present invention bind to the RNA product produced by RNA amplification. Further, as discussed in Section III, *supra*, claim 1 has been amended to clarify that RNA amplification is used to amplify the oligonucleotide and the amplified oligonucleotide is then contacted with a fluorescent dye which binds RNA directly.

MPEP § 2131 is clear, to anticipate a claim the reference

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must teach every element of the claimed invention. Since Sano et al. do not teach or suggest use of fluorescent dyes which bind to RNA in their DNA assay, nor do they teach RNA amplification in their DNA amplification method, this reference cannot anticipate the claims as amended.

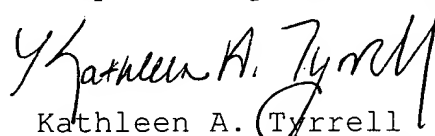
Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1 has been amended as follows:

1. (Twice amended) A method for detecting molecules expressing a selected epitope in a sample comprising:

(a) immobilizing a molecule expressing a selected epitope in a sample to a selected surface;

(b) contacting the surface with an epitope detector so that the epitope detector binds to immobilized molecules on the surface, said epitope detector comprising an oligonucleotide attached to a monoclonal antibody for the selected epitope, a single chain Fv for the epitope or a constrained epitope specific CDR, CDR mimetic or engineered CDR structure;

(c) amplifying the oligonucleotide of said epitope detector by RNA amplification;

(d) contacting the amplified oligonucleotide with a fluorescent dye which binds to RNA directly and stains the oligonucleotide; and

(e) measuring fluorescence emitted from the stained oligonucleotide which is indicative of epitope detector bound to the surface and molecules expressing the selected epitope in the sample.